IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PERNIX IRELAND PAIN LTD and PERNIX THERAPEUTICS, LLC,	)	
Plaintiffs,	)	
v.	)	
	)	C.A. No. _____
ALVOGEN MALTA OPERATIONS LTD.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Pernix Ireland Pain Ltd. ("Pernix Ireland") and Pernix Therapeutics, LLC ("Pernix Therapeutics") (collectively, "Plaintiffs"), for their Complaint against Defendant Alvogen Malta Operations Ltd. ("Alvogen"), hereby allege as follows:

THE PARTIES

1. Pernix Ireland is a corporation organized and existing under the laws of Ireland, having its principal place of business at Pembroke House, Dublin 2, Ireland.

2. Pernix Therapeutics is a corporation organized and existing under the laws of Louisiana having its principal place of business at 10 North Park Place, Suite 201, Morristown, New Jersey 07960.

3. On information and belief, Alvogen is a corporation organized and existing under the laws of Malta.

4. On information and belief, Alvogen, is in the business of among other things, manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products that it distributes in the State of Delaware and throughout the United States.

NATURE OF ACTION

5. This is an action for infringement of United States Patent No. 9,265,760 ("the '760 patent") under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*, including 35 U.S.C. §§ 271(e)(2), 271(a), 271(b) and/or 271(c), and for a declaratory judgment of infringement of the '760 patent under 28 U.S.C. §§ 2201 and 2202. A true and correct copy of the '760 patent is attached as Exhibit A.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201 and 2202.

7. This Court has personal jurisdiction over Alvogen by virtue of the fact that, *inter alia*, it has committed the tortious act of patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) that has led to foreseeable harm and injury to Plaintiffs in the State of Delaware, and throughout the United States.

8. This Court also has personal jurisdiction over Alvogen by virtue of the fact that Alvogen previously submitted to the jurisdiction of this Court and availed itself of this Court by consenting to this Court's jurisdiction and asserting counterclaims in a civil action initiated in this jurisdiction involving the same Abbreviated New Drug Application ("ANDA") and pharmaceutical product at issue here. *See, e.g.*, *Recro Gainesville LLC v. Alvogen Malta Operations Ltd.*, C.A. No. 14-cv-1364-GMS, D.I. 7 (D. Del. Nov. 25, 2014), D.I. 42 (D. Del. Dec. 2, 2015) (consenting to suit regarding ANDA No. 206986 and Zohydro® ER).

9. This Court also has personal jurisdiction over Alvogen by virtue of the fact that Alvogen is at home in Delaware as reflected by the fact that, on information and belief, it regularly does or solicits business in Delaware, engages in other persistent courses of conduct in

Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, including by selling its pharmaceutical products in Delaware and, therefore, can reasonably expect to be subject to jurisdiction in the Delaware courts. Among other things, on information and belief, Alvogen conducts marketing and sales activities in the State of Delaware, including, but not limited to, distribution, marketing, and sales of pharmaceutical products to Delaware residents that are continuous and systematic.

10. On information and belief, this Court also has personal jurisdiction over Alvogen under Federal Rule of Civil Procedure 4(k)(2).

11. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

FACTUAL BACKGROUND

12. Pernix Ireland is the holder of an approved New Drug Application ("NDA") No. 202880 for Zohydro® ER extended-release capsules. The United States Food and Drug Administration ("FDA") approved NDA No. 202880 on October 25, 2013. Zohydro® ER capsules contain hydrocodone bitartrate and are indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

13. On February 23, 2016, the '760 patent, entitled "Treating Pain in Patients with Hepatic Impairment," was duly and legally issued to Pernix Ireland. The '760 Patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") for Zohydro® ER capsules. Pernix Therapeutics is the exclusive licensee of the '760 patent and is the sole distributor of Zohydro® ER capsules in the United States.

14. U.S. Patent Nos. 6,228,398 ("the '398 patent"), 6,902,742 ("the '742 patent"),

and 9,132,096 ("the '096 patent") are also listed in the Orange Book for Zohydro® ER capsules.

15. On information and belief, Alvogen submitted ANDA No. 206986 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of hydrocodone bitartrate extended-release capsules in 10, 15, 20, 30, 40, and 50 mg strengths ("Alvogen Generic Product"), as generic versions of the Zohydro® ER 10, 15, 20, 30, 40, and 50 mg capsules.

16. By letters dated September 26, 2014 and December 15, 2015 ("the Alvogen-Recro Notice Letters"), Alvogen advised Recro Tech., LLC ("Recro"), the owner of the '398, '742, and '096 patents, and Pernix Ireland that it had submitted ANDA No. 206986 to the FDA seeking approval to manufacture, use, or sell the Alvogen Generic Product prior to the expiration of the '398, '742, and '096 patents.

17. The Alvogen-Recro Notice Letters also advised Recro and Pernix Ireland that Alvogen's ANDA submission included a certification under 21 U.S.C. § 355(j)(2)(B)(iv) that, in Alvogen's opinion, the claims of the '398, '742, and '096 patents are invalid, unenforceable and/or not infringed.

18. Recro and its predecessors previously filed an action in this Court asserting that Alvogen's submission of ANDA No. 206986 to the FDA seeking approval to manufacture, use, or sell the Alvogen Generic Product constitutes infringement of '398 and '742 patents. This action, filed on November 3, 2014 (C.A. No. 14-cv-1364-GMS) is ongoing.

19. The 30-month stay of FDA approval on the Alvogen Generic Product pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) is set to expire on March 29, 2017.

20. The '760 patent had not issued at the time Alvogen submitted its certifications under 21 U.S.C. § 355(j)(2)(B) with respect to the '398, '742, and '096 patents.

21. On February 23, 2016, Plaintiffs notified Alvogen of the existence of the '760 patent. Alvogen did not respond to Plaintiffs' notification.

22. On information and belief, Alvogen has made and will continue to make substantial and meaningful preparations to engage in the commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States a product that will be administered to patients using a method of treatment patented by the '760 patent prior to its expiration.

23. On information and belief, Alvogen's preparations include, but are not limited to, the development of the Alvogen Generic Product and the filing of ANDA No. 206986. These preparations indicate a refusal to change its course of action in the face of acts by Plaintiffs.

24. On information and belief, Alvogen continues to seek approval of ANDA No. 206986, and upon approval by the FDA, Alvogen intends to immediately engage in the commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States the Alvogen Generic Product that will be administered to patients using a method of treatment patented by the '760 patent prior to its expiration.

25. On information and belief, the method of treatment patented by the '760 patent is an essential component of administering the Alvogen Generic Product to patients.

26. On information and belief, Alvogen will direct or control the treatment of patients using the Alvogen Generic Product with methods claimed in the '760 patent, after the FDA approves ANDA No. 206986. On information and belief, this will occur at Alvogen's active behest and with its intent, knowledge and encouragement. On information and belief, Alvogen will actively encourage, aid and abet this treatment with knowledge that it is in contravention of Plaintiffs' rights under the '760 patent.

27. On information and belief, Alvogen will knowingly provide the Alvogen

Generic Product with instructions for use that substantially copy the instructions for Zohydro® ER capsules, including instructions for treating patients using methods claimed in the '760 patent.

28. On information and belief, Alvogen knows the instructions that will accompany the Alvogen Generic Product will induce and/or contribute to others using the Alvogen Generic Product in the manner set forth in the instructions.

29. On information and belief, physicians, health care providers, and/or patients will directly infringe one or more claims of the '760 patent by using the Alvogen Generic Product in accordance with the instructions provided by Alvogen, after the FDA approves ANDA No. 206986.

30. On information and belief, Alvogen specifically intends that physicians, health care providers, and/or patients will use the Alvogen Generic Product in accordance with the instructions provided by Alvogen to directly infringe one or more claims of the '760 patent. Alvogen therefore will actively induce and/or contribute to infringement of the '760 patent.

31. On information and belief, Alvogen knowingly has taken and intends to take active steps to induce and/or contribute to physicians, health care providers, and/or patients using the Alvogen Generic Product in a manner that directly infringes at least one claim of the '760 patent.

32. On information and belief, Alvogen designed the Alvogen Generic Product for use in a way that would infringe the '760 patent and will instruct users of the Alvogen Generic Product to use the Alvogen Generic Product in a way that would infringe the '760 patent.

COUNT I

Infringement of the '760 Patent Under 35 U.S.C. § 271(e)(2)

33. Plaintiffs incorporate each of the preceding paragraphs 1 to 32 as if fully set forth herein.

34. Alvogen submitted ANDA No. 206986 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use or have used, offer for sale, sale, and/or importation of the Alvogen Generic Product throughout the United States, including Delaware, prior to patent expiry. By submitting and maintaining the application, Alvogen committed an act of infringement with respect to the '760 patent, under 35 U.S.C. § 271(e)(2)(A).

35. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry will constitute direct infringement, contributory infringement and/or active inducement of infringement of the '760 patent under 35 U.S.C. §§ 271(a), 271(b) and/or 271(c).

36. The use of the Alvogen Generic Product by physicians, health care providers, and/or patients prior to patent expiry will directly infringe one or more claims of the '760 patent.

37. Alvogen will direct, control, encourage, aid and/or abet the direct infringement of one or more claims of the '760 patent by and through the commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry.

38. On information and belief, Alvogen knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry will actively induce direct infringement of one or more claims of the '760 patent.

39. Alvogen's acts described in paragraphs 37-38 will be performed with

knowledge of the '760 patent and with intent to encourage infringement prior to patent expiry.

40. On information and belief, Alvogen knows or should know the Alvogen Generic Product will be especially made or especially adapted for use in an infringement of the '760 patent, and it is not a staple article or commodity of commerce suitable for substantial non-infringing use.

41. On information and belief, Alvogen knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry will contribute to the direct infringement of one or more claims of the '760 patent.

42. Alvogen's acts described in paragraphs 40-41 will be performed with knowledge of the '760 patent and with intent to encourage infringement prior to patent expiry.

43. Alvogen was aware of the existence of the '760 patent prior to the filing date of this Complaint. This is an exceptional case.

44. Alvogen's commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to the expiration of the '760 patent in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

45. Unless Alvogen is enjoined from directly infringing, contributing to the infringement, and/or actively inducing the infringement of the '760 patent, sales of the Alvogen Generic Product prior to the expiration of the '760 patent will cause Plaintiffs irreparable injury for which damages are an inadequate remedy.

COUNT II

Declaratory Judgment of Infringement of the '760 Patent Under 35 U.S.C. §§ 271(a), (b) and/or (c)

46. Plaintiffs incorporate each of the preceding paragraphs 1 to 45 as if fully set forth herein.

47. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

48. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

49. Alvogen has made, and will continue to make, substantial preparation in the United States to manufacture, use or have used, offer for sale, sell, and/or import the Alvogen Generic Product into the United States prior to the expiration of the '760 patent.

50. Alvogen's actions, including, but not limited to, the filing of ANDA No. 206986 and engaging in litigation to manufacture, use or have used, offer for sale, sell, and/or import the Alvogen Generic Product into the United States prior to the expiration of the '760 patent indicate a refusal to change the course of its action in the face of acts by Plaintiffs.

51. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry will constitute direct infringement, contributory infringement and/or active inducement of infringement of at least claims 1, 5, and 6 of the '760 patent under 35 U.S.C. §§ 271(a), 271(b) and/or 271(c).

52. On information and belief, Alvogen intends to, and will, directly infringe, contribute to the infringement, and/or actively induce the infringement of at least claims 1, 5, and 6 of the '760 patent when ANDA No. 206986 is approved by the FDA, and plans and intends to, and will, do so immediately and imminently upon approval.

53. Claim 1 of the '760 patent reads as follows:

> 1. A method of treating pain in a patient having mild or moderate hepatic impairment, the method comprising: administering to the patient having mild or moderate hepatic impairment a starting dose of an oral dosage unit having hydrocodone bitartrate as the only active ingredient, wherein the dosage unit

> comprises an extended release formulation of hydrocodone bitartrate, and wherein the starting dose is not adjusted relative to a patient without hepatic impairment.

54. On information and belief, the Alvogen Generic Product is "an oral dosage unit having hydrocodone bitartrate as the only active ingredient, wherein the dosage unit comprises an extended release formulation of hydrocodone bitartrate," and will be sold together with labeling that does not differ significantly from the labeling for Zohydro® ER capsules, which directs that: "No adjustment in starting dose with ZOHYDRO ER is required in patients with mild or moderate hepatic impairment."

55. Alvogen will thus direct, control, encourage, aid and/or abet the direct infringement of claim 1 of the '760 patent by and through the commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry, and the use of the Alvogen Generic Product by physicians, health care providers, and/or patients prior to patent expiry will thus directly infringe claim 1 of the '760 patent.

56. Claim 5 of the '760 patent reads as follows:

> 5. The method of claim 1, wherein the starting dose of the dosage unit comprises 15 mg or more of hydrocodone bitartrate.

57. Claim 6 of the '760 patent reads as follows:

> 6. The method of claim 5, wherein the starting dose of the dosage unit comprises 20, 30 or 40 mg of hydrocodone bitartrate.

58. As set forth in paragraph 15 above, Alvogen is seeking approval to engage in the commercial manufacture, use, and sale of hydrocodone bitartrate extended-release capsules in 10, 15, 20, 30, 40, and 50 mg strengths.

59. Alvogen will thus direct, control, encourage, aid and/or abet the direct infringement of claims 5 and 6 of the '760 patent by and through the commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent

expiry, and the use of the Alvogen Generic Product by physicians, health care providers, and/or patients prior to patent expiry will thus directly infringe claims 5 and 6 of the '760 patent.

60. On information and belief, Alvogen knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry will actively induce direct infringement of at least claims 1, 5, and 6 of the '760 patent.

61. Alvogen's acts described in paragraphs 55, 59 and 60 will be performed with knowledge of the '760 patent and with intent to encourage infringement of at least claims 1, 5, and 6 of the '760 patent prior to patent expiry.

62. On information and belief, Alvogen knows or should know the Alvogen Generic Product will be especially made or especially adapted for use in an infringement of at least claims 1, 5, and 6 of the '760 patent, and it is not a staple article or commodity of commerce suitable for substantial non-infringing use.

63. On information and belief, Alvogen knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry will contribute to the direct infringement of at least claims 1, 5, and 6 of the '760 patent.

64. Alvogen's acts described in paragraphs 62-63 will be performed with knowledge of the '760 patent and with intent to encourage infringement of at least claims 1, 5, and 6 of the '760 patent prior to patent expiry.

65. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Alvogen Generic Product prior to patent expiry by Alvogen will constitute direct infringement,

contributory infringement, and/or active inducement of infringement of at least claims 1, 5, and 6 of the '760 patent.

66. Alvogen was aware of the existence of the '760 patent prior to the filing date of this Complaint. This is an exceptional case.

67. Alvogen's commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to the expiration of the '760 patent in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

68. Unless Alvogen is enjoined from directly infringing, contributing to the infringement, and/or actively inducing the infringement of the '760 patent, sales of the Alvogen Generic Product prior to the expiration of the '760 patent will cause Plaintiffs irreparable injury for which damages are an inadequate remedy.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. that judgment be entered that Alvogen has infringed the '760 patent;

B. that an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 206986 shall be a date that is not earlier than the expiration date of the '760 patent, inclusive of any extensions;

C. that, prior to March 29, 2017 (the expiration of the 30-month stay referenced in paragraph 19), a preliminary injunction be issued enjoining Alvogen, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product within or into the United States until the resolution of the claims associated with this lawsuit, including any appeals;

D. that an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Alvogen, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product within or into the United States prior to the expiration date of the '760 patent, inclusive of any extensions;

E. that damages or other monetary relief be awarded to Plaintiffs under 35 U.S.C. § 271(e)(4)(C) as appropriate with respect to the '760 patent;

F. that a declaration be issued under 28 U.S.C. § 2201 that if Alvogen, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry, it will constitute an act of infringement of the '760 patent;

G. that a declaration be issued that this is an exceptional case and an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

H. costs and expenses in this action; and

I. such other and further relief as the Court may deem just and proper.

Dated: March 4, 2016

MCCARTER & ENGLISH LLP

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